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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/846,565	WINTERS, R. EDWARD	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-8,15,16 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8, 15, 16, and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's amendment filed February 13, 2009 has overcome the 112 1st rejections.

Applicant's arguments filed February 13, 2009 with respect to the prior art applied have been fully considered but they are not persuasive.

The applicant has argued that Dubrul (US 6,258,115 B1) in view of Brown (US 6,093,199) and Hieshima (US 6,361,558 B1) do not disclose the step of determining a nominal opening size of an artery and installing memory properties to retain the opening size. The examiner disagrees. The applicant argues that Dubrul does not disclose *measuring* the artery to determine a size. However, a measurement step is not claimed and applicant does not have support for physically measuring the artery either. Applicant's specification provides support for using memory materials that are preformed to a shape to match the structure in which the device is placed, and when placed there, the hoop reforms to its preformed shape. The step of determining the size of the artery is not specifically disclosed/recited by the applicant, however it is inherent since memory materials work in way in that they are programmed/shape set to have a particular size/shape that the size/shape of the artery must have been determined. Because the stents are being set/programmed/preformed, a desired diameter for the vessel has inherently been determined by the surgeon, that determination is inherent since a specific shape/size is disclosed to be programmed/set into the stent. This inherent determination of the applicants stent is also inherent in Dubrul, since Dubrul also uses such memory materials that require shape setting/programming (col.6, lines 37-40, 57-67; col.7, line 1; col.8, lines 49-68; disclosed to be *programmed* to take a particular shape, which includes spacing and diameter). Because Dubrul's

stent uses memory material that has been *programmed to have a specific shape* prior to implantation, and the stents are shown in the figures to have a good fit against the vessels (see fig.5c for example) it is considered inherent that the artery size has been determined as such is needed to program the shape of the memory stent for a proper fit. Brown, which is used as a teaching reference with Dubrul, further elaborates on how shape memory materials work, having a preformed and expanded shape to match the shape of the vessel in to which it is inserted (col.3, lines 13-26; col.4, lines 48-53, wherein Brown discloses "anchoring elements are *formed* from a tightly coiled small radius coil (not shown) that is *wound* into a secondary helical coil configuration having a larger radius *approximately equal to the radius of the patient's vasculature at the target site*" this is necessary for proper anchoring).

The applicant further argues that Brown is not combinable with Dubrul since stents of Brown and Dubrul are used for different purposes. The examiner disagrees. Both Brown and Dubrul disclose stents that may be in the general form of helical coils and are placed in the vasculature and provide support to the vessel. They are in the same field of helical stents and their specific features are applicable to one another. Even though Brown's stent is used near an aneurysm in the vasculature, the anchor elements of the stent still provide anchoring and support, preventing the stent from moving. Brown's stent may have a different placement in the vasculature (near an aneurysm), however it is of the same class of stent structure and within the cardiovascular system, just as Dubrul's stent is.

The applicant has argued that Brown's stent does not reform and radially support the vessel. The examiner disagrees. As Brown's stent is formed of a shape memory material, just as applicants is, it does reform to its set or programmed shape upon delivery, see col.3, lines 12-27,

col.5, lines 48-59, "it has a memory that returns the elements to their coiled, expanded configuration, and thus anchor itself to the patients vasculature". As anchoring elements 30 are termed "anchoring" and are disclosed to "anchor itself to the patients vasculature", it is clear that radial support is provided. As Brown's stent (30) does reform and radially support the vessel, it is applicable to Dubrul and does not teach away and the combination of Brown' primary shape on Dubrul's helical coil stent would not render the stents inoperable.

The applicant has argued that Neuss (US 5,536,274) does not disclose the step of determining the size of the artery. The examiner disagrees. Nuess also uses memory materials that have a preformed shape set into them prior to implantation (See abstract, "pre-formed" spiral shape; col.2, line 60-col.3 line12, heat setting a shape) and are shown in the figures to have a shape that fits to the size of the artery. As Nuess's stent is a memory material, just as applicant's is, that is *preformed* to a specific shape, thus it is considered inherent that the artery size has been determined as such is needed to program the shape of the memory stent for a proper fit in the artery (proper fit is shown in Nuess's figures).

The applicant has argued that Hieshima's (US 6,361,558 B1) helical stent (having a secondary shape shown in fig.1 for example of a simple coil) is incapable of also having a primary shape. The examiner disagrees. The coil is a wire made of the same material as Brown, thus Brown's additional primary shape on coil structures is applicable to Hieshima and would be capable of such a formation since Hieshima's material and shape of secondary coil are the same as Brown's secondary coil. Hieshima discloses a coiled stent with instilled memory properties (col.3, lines 30-45) however has only a secondary coil shape, not a primary. Brown teaches a primary coil shape in addition to the secondary shape that is also instilled with memory

properties. Hieshima and Brown are believed by the examiner to be combinable. The applicant further argues that Hieshima does not disclose the step of determining the artery size, however this is considered inherent when working with shape memory materials (since they are preformed and shape set to a particular shape prior to implantation; some size inherently was determined) and with implants, since a proper fit must exist in order for the stent to be inserted in a specific location.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-8, 15, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul (US 6,258,115 B1, cited previously) in view of Brown (US 6,093,199, cited previously) and Hieshima et al. (US 6,361,558 B1, cited previously). Dubrul discloses a procedure for opening a coronary artery (carotid or any other blood vessel in the body; thus includes coronary; col.4, lines 46-48; col.5, lines 11-14) having a nominal opening size (fig.1; at location of numeral 10 or 12 is seen) adjacent a target (fig.1; numeral 13; col.1, lines 16-20) comprising the steps of determining an artery nominal size (size near 10 and 12 in fig.1; the determination of this size is inherent in the shape memory materials used by Dubrul since they are *programmed* to have a specific shape, that specific shape has already been determined inherently), providing a preformed hoop coil stent having instilled memory properties (stent embodiment referred herein not shown in the figures, however disclosed at col.8, lines 49-61;

disclosed to have a programmed/preformed shape, col.6, line 57-col.7 line 1) and inserting the hoop stent and delivery means into the artery at the target site such that the coil reforms to its programmed shape and supports the target (13; see fig.1; example stent shown placed at target site in fig.5b), removing the delivery means (fig.5c shows delivery means removed). Dubrul discloses the hoop stent to have an open spacing greater than the rest of the hoop stent spacing placed at a branch vessel to allow flow through the open spacing (col.8, lines 51-59). Dubrul discloses balloon dilation prior to hoop insertion (col.10, lines 7-10).

Dubrul discloses the method substantially as claimed, however discloses the preformed memory hoop stent to have a secondary coil shape only, and not a primary coil shape. Brown teaches in the same field of preformed memory hoop stents for placement in blood vessels, the use of a helical stent (30; all figures) that is also self expanding shape memory (col.3, lines 12-27; col.4, lines 48-53), having both a primary *and* secondary coil in order to provide increased strength to support the vessel and the ability to delivery at a smaller diameter (over a rod or within a catheter in a linear shape-creating a lower profile with reduced trauma), col.4, lines 49-67; col.3, lines 12-27. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dubrul's method of opening an artery with a preformed memory hoop stent having a secondary coil shape, with Brown's teaching of using a primary coil *in addition* to a secondary coil on memory hoop stents in order to provide a method that better supports the vessel wall with reduced trauma due to the low delivery and higher strength of the improved hoop stent. See Neuss (US 5,536,274, cited previously) as additional evidence of another example of use of a primary and secondary coil structure on a helical stent for use of holding open a blood vessel (col.6, lines 1-3, 44-48; fig.1, 3).

Dubrul also does not disclose the hoop stent to have a rounded end. Hieshima teaches in the same field of hoop stents (10; see fig.1) for use in blood vessels (abstract), the use of a rounded end (28) in order to reduce trauma during insertion into the body by avoiding sharp edges that may catch on the vessel wall (col.4, lines 18-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dubrul's method of opening an artery by insertion of a hoop stent, with Hieshima's teaching of placing rounded ends on hoops stents, in order to provide a reduced trauma surgery.

Claims 5-8 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuss (US 5,536,274, cited previously) in view of Fischell et al. (US 4,768,507, cited previously). Neuss discloses a procedure substantially as claimed. Neuss discloses inserting a preformed hoop stent having the primary (2) and secondary (1) coil shapes claimed (fig.1, 3; col.6, lines 44-47), the hoop having a rounded end (seen in fig.11a) and memory properties instilled into the stent ("preformed" abstract; heat set to a specific shape, col.2, line 60-col.3 line 12), inserting the hoop stent by a delivery means (14, 16, or 19; fig.11a-11e) into an artery and removing the delivery means so that the hoop supports the artery in the secondary coil shape (keeping an organ pathway open, col.6, lines 1-3). Nuess's method is considered to have inherently determined the artery size prior to insertion, since Nuess's stent is seen with a proper fit in the figures and Nuess makes use of memory materials that have been preformed, thus programmed to have a particular shape prior to implantation. (Such size determinations of arteries are well known to occur, are considered inherent since they must occur if a stent is to fit properly within a vessel; Brown US 6,093,199 is cited herein as additional evidence which discloses memory materials preformed

with a size the shape of the vessel, thus the vessel shape being determined prior inherently; col.3, lines 12-27; col.4, lines 48-53). Neuss discloses the method substantially as claimed by placement of a hoop stent into a vessel to support the vessel, however Neuss does not disclose *opening* the artery (by predilation or stent expansion). Placement of stents in occluded or narrowed areas of vessels is well known in the art and one of the main purposes of stents. Fischell teaches in the same field of hoop stents, the use of helical type hoops stents in areas where occlusions or narrowing is present (fig.1a) in order to widen the vessel wall to its normal size to provide optimal blood flow (fig.2) and prevent restenosis (col.2, lines 1-3, 53-59; col.3, lines 22-46; col.4, lines 57-64). Fischell does this by balloon pre dilation to expand/open the lumen prior to stent placement in order to prepare the lumen to receive the stent (col.3, lines 25-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Neuss's method of implanting a hoop stent with the shape claimed into a vessel to support the vessel, with Fischell's teaching of pre-dilation to open the artery prior to stent placement in order to widen the area for flow and restenosis prevention.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hieshima et al. (US 6,361,558 B1, cited previously) in view of Brown (US 6,093,199, cited previously). Hieshima discloses a procedure for opening a coronary artery (any blood vessel in the body; thus includes coronary;col.3, lines 26-29) having a nominal opening size (normal size, not narrowed) adjacent a target (narrowed or occluded site; col.3, lines 26-29; col.2, lines 14-16) comprising the steps of determining an artery nominal size (this is considered an inherent step since Hieshima's stent is shown sized correctly to the vessel in the figures and since memory materials are used

which require programming a specific size/shape into the stent prior to implantation), providing a hoop coil stent (10; fig.1) having memory and a rounded end (28), and inserting the hoop stent and delivery means into the artery at the target site (fig.4 or 9 for example), removing the delivery means (fig.8, 9) such that the hoop stent reforms to its preformed shape and supports the artery (opening narrowed vessels, col.3, lines 26-30; col.4 line 66-col.5 line 5; col.6, lines 3-9; see figs).

Hieshima discloses the method substantially as claimed, however discloses the hoop stent to have a secondary coil shape only, and not a primary coil shape. Brown teaches in the same field of hoop stents for placement in blood vessels, the use of a helical stent (30; all figures) having both a primary *and* secondary coil preformed into the stent in order to provide increased strength to support the vessel and the ability to delivery at a smaller diameter (over a rod or within a catheter in a linear shape-creating a lower profile with reduced trauma), col.4, lines 49-67; col.3, lines 12-27. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Hieshima's method of opening an artery with a hoop stent having a secondary coil, with Brown's teaching of using and memory instilling a primary coil in addition to a secondary coil on hoop stents in order to provide a method that better supports the vessel wall with reduced trauma due to the low delivery and higher strength of the improved hoop stent.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738